REMARKS

Formal Matters

In the specification at page 1, line 7, correction of inadvertent error in claim to priority and at page 60, line 17, typographical error of the ATCC deposit number have been amended.

Amendment to paragraph 1, page 1 (correction of inadvertent error in claim to priority) was initiated prior to issuance of the final rejection and entry of the amendment after final rejection is respectfully requested.

Entry of the amendment on page 60 of the specification after final rejection is respectfully requested to correct an inadvertent typographical error. No new matter is added by the amendment. Applicants herewith submit support for the amendment to page 60, lines 12-17 of the specification in which the ATCC designation 74,841 was corrected to read 75,841. The correct ATCC designation is shown on the enclosed sheet as deposited on behalf of Genentech, Inc. Case No. 894P1, which is the same as U.S. application serial no. 08/286,304, filed August 5, 1994, now U.S. Patent No. 5,571,893, issued November 5, 1996 to which the instant application claims priority under 35 USC § 120.

Claims 1-3, 24-29, and 31-41 are pending in the application. Claims 2, 4-23 and 30 have been previously canceled. Claims 1 and 28 are newly amended herein. No new matter is added by the amendments. Support for the amendments is found throughout the specification, such as, for example, at page 13, lines 19-22; page 18, lines 22-35; page 38, line 27 to page 39, line 18 (Example1); page 50, line 20 to page 52, line 15 (Example 2); and page 52, lines 16-29 (Example 3).

In view of the Examiner's earlier restriction requirement, applicant retains the right to present withdrawn claims 2 and 4-23 in a divisional application.

Priority

The objection to the amendment filed 2/27/03 is still objected to under 35 U.S.C. 132 as allegedly introducing new matter. The Examiner asserts that when a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application (citing Dart Industries v. Banner, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980), "Dart Industries"). Applicants respectfully disagree because Dart Industries involved a claim to priority of a continuation-in-part application which contained new matter, the incorporation of which would have changed the invention disclosure. This is completely different from the Applicants' situation making reliance on the Dart Industries case inappropriate here. Applicants' The present

application is a continuation of parent application (09/648,183) which is a continuation of an application to which applicant previously claimed priority (09/234,730). Unlike in the Dart Industries case, there is no change to the invention disclosure by a claim to priority of a continuation application. Because there is no amendment to the invention disclosure by the amended priority claim in this application, the Dart Industries case does not apply and the objection should be withdrawn.

Without acquiescing to the objection and merely to narrow the issues on appeal should an appeal become necessary, Applicants have amended paragraph 1 to recite the priority claim to parent continuation application in a way that does not recite its incorporation by reference. Withdrawal of the objection is respectfully requested.

Withdrawal of Rejections Under 35 U.S.C. § 112, First Paragraph and 35 U.S.C. § 102(a) (Joho et al.)

Applicants gratefully acknowledge withdrawal of the rejections under Sections 112, first paragraph, and Section 102(a) (citing Joho et al.) as stated on pages 3 and 4 of the Office Action.

ALLEGED NEW GROUND FOR REJECTION

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1, 3, 24-29, 31-41 are rejected under 35 U.S.C. § 112, written description, because the specification allegedly fails to describe any other nucleic acid, other than SEQ ID NO:1 or its complement SEQ ID NO:2 (as stated by the Examiner in Paper No. 8, page 5), which encodes SEQ ID NO:3. Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

Applicants claim a method of screening for higher expression level of a nucleic acid sequence SEQ ID NO:1 or SEQ ID NO:2 by, in part, detecting the level of expression of the nucleic acid sequence wherein the detecting comprises contacting the nucleic acid with a detectable nucleic acid comprising at least 20 nucleotides of SEQ ID NO:1 or SEQ ID NO:2. Applicants further claim a method of detecting increased copy number of a nucleic acid sequence SEQ ID NO:1 or its complement SEQ ID NO:2, wherein the detecting comprises contacting the nucleic acid with a detectable nucleic acid comprising at least 20 nucleotides of SEQ ID NO:1 or SEQ ID NO:2. Support for these recitations is found throughout the specification and at the pages noted above in the Formal Matters section.

Applicants respectfully submit that one of ordinary skill in the art can readily determine sequences encoding SEQ ID NO:3 (the deduced amino acid sequence from SEQ ID NO:1) and that with

such ability Applicants originally filed disclosure clearly indicates that Applicant was in possession of the invention at the time of filing.

Applicants make amendments to the claims without acquiescing to the Examiner's rejection and merely to narrow the issues on appeal should an appeal become necessary. Entry of the amendments is respectfully requested.

Applicants respectfully submit that the claim amendments overcome the rejection under section 112, first paragraph, written description. Withdrawal of the rejection and allowance of the claims is respectfully requested.

SUMMARY

Claims 1-3, 24-29, and 31-41 are pending in the application. Claims 4-23 and 30 were previously canceled. Pages 1 and 60 of the specification and Claims 1 and 28 are amended herein. The amendments are made to correct inadvertent typographical errors and to narrow the issues on appeal should an appeal become necessary. Entry of the amendments is respectfully requested.

Applicants have overcome the objection to the specification (regarding a claim to priority) and a new rejection under Section 112, first paragraph. Withdrawal of the objection and rejection and allowance of the claims is respectfully requested.

If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter and petition for a three-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
GENENTECH, INC.

Date: August 4, 2004

By: _____
Deirdre L. Conley
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Telephone No. (650) 225-2066

Appendix of Claims

1. (Three Times Amended) A method of screening for higher expression level of a nucleic acid sequence SEQ ID NO:1 or its complement, SEQ ID NO:2, in tumor tissue of a mammal, the method comprising:

(a) detecting the level of expression of the nucleic acid sequence in a test sample of tumor tissue cells obtained from the mammal, wherein the detecting is by contacting the nucleic acid with a detectable nucleic acid comprising at least twenty nucleotides of SEQ ID NO:1 or SEQ ID NO:2;

(b) detecting, as in step (a), the level of expression of the nucleic acid sequence in a control sample of tissue cells of the same cell type; and

(c) comparing the expression level of the nucleic acid sequence in the test cells with the expression level in the control cells and demonstrating higher expression level in the test sample.

2. (Canceled)

3. (Previously amended) The method of claim 1 wherein said test sample is obtained from an individual suspected to have neoplastic cell growth or proliferation.

4.-23. (Canceled)

24. (Previously added) The method of claim 3 wherein the test sample is from a human.

25. (Previously added and amended) The method of claim 1 wherein the expression level of the nucleic acid sequence in the test sample cells is at least two-fold greater than in the control cells.

26. (Previously added) The method of claim 1 wherein the test sample is from cancerous tissue.

27. (Previously added and amended) The method of claim 26 wherein the cancerous tissue is selected from the group consisting of breast cancer, prostate cancer, colon cancer, squamous cell cancer, small-cell lung cancer, non-small-cell lung cancer, gastrointestinal cancer, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer, bladder cancer, hepatoma, colorectal cancer, endometrial carcinoma, salivary gland carcinoma, kidney cancer, vulval cancer, thyroid cancer, and head and neck carcinoma.

28. (Previously added and twice amended) A method of detecting increased copy number of a nucleic acid sequence SEQ ID NO:1 or its complement, SEQ ID NO:2, in tumor tissue of a mammal, the method comprising:

(a) detecting the number of copies of the nucleic acid sequence in a test sample of tumor tissue cells obtained from the mammal, wherein the detecting is by contacting the nucleic acid with a detectable nucleic acid comprising at least twenty nucleotides of SEQ ID NO:1 or SEQ ID NO:2;

(b) detecting the number of copies of a nucleic acid marker sequence on the chromosome encoding the nucleic acid sequence in the test sample, which marker gene is not amplified; and

(c) comparing the copy number of the nucleic acid sequence in the test cells with the copy number of the marker sequence and demonstrating increased copy number of the nucleic acid sequence in the test sample.

29. (Previously added and twice amended) The method of claim 28 wherein the marker sequence is in Chromosome 16 in chromosomal regions selected from the group consisting of regions P7, P55, P89, P90, P92, P93, P94, P95, P99, P154, and P208.

30. (Canceled)

31. (Previously added) The method of claim 28 wherein said test sample is obtained from an individual suspected to have neoplastic cell growth or proliferation.

32. (Previously added) The method of claim 31 wherein the test sample is from a human.

33. (Previously added and amended) The method of claim 26 wherein the nucleic acid sequence copy number in the test sample cells is at least two-fold greater than the copy number of unamplified marker sequences.

34. (Previously added) The method of claim 28 wherein the test sample is from cancerous tissue.

35. (Previously added and amended) The method of claim 28 wherein the cancerous tissue is selected from the group consisting of breast cancer, prostate cancer, colon cancer, squamous cell cancer, small-cell

lung cancer, non-small-cell lung cancer, gastrointestinal cancer, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer, bladder cancer, hepatoma, colorectal cancer, endometrial carcinoma, salivary gland carcinoma, kidney cancer, vulval cancer, thyroid cancer, and head and neck carcinoma.

36. (Previously added) The method of claim 1, wherein detecting is a method selected from the group consisting of high stringency nucleic acid hybridization and polymerase chain reaction (PCR)-based methods.

37. (Previously added) The method of claim 36, wherein the detecting methods are selected from the group consisting of *in situ* hybridization, quantitative PCR, RT-PCR, and comparative genomic hybridization.

38. (Previously added) The method of claim 1, wherein the nucleic acid sequence is amplified in the test sample cells.

39. (Previously added) The method of claim 28, wherein detecting is a method selected from the group consisting of high stringency nucleic acid hybridization and polymerase chain reaction (PCR)-based methods.

40. (Previously added) The method of claim 39, wherein the detecting methods are selected from the group consisting of *in situ* hybridization, quantitative PCR, RT-PCR, and comparative genomic hybridization.

41. (Previously added) The method of claim 28, wherein the nucleic acid sequence is amplified in the test sample cells.

PATENT DOCKET P2533D1
SERIAL NO. 09/648,561
ATCC DEPOSIT

American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Genentech, Inc.
Attention: Stephen Raines
460 Point San Bruno Boulevard
South San Francisco, CA 94080

RECEIVED
AUG 15 1994
GENENTECH, INC. LEGAL DEPT.

Deposited on Behalf of: Genentech, Inc. (Case No. 894P1)

Identification Reference by Depositor:	**ATCC Designation**
Plasmid, pBSSK+.hu.CT1.h5	75841

The deposit was accompanied by: __ a scientific description __ a proposed taxonomic description indicated above.

The deposit was received July 26, 1994 by this International Depository Authority and has been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested August 4, 1994. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Harold D. Hatt **Date:** August 10, 1994

Harold D. Hatt, Acting Head, ATCC Patent Depository

cc: Janet E. Hasak ✓

Form BP4/9

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